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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,271	06/02/2005	Jean-Claude Sirard	2590-112	6291

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EXAMINER	
GANGLE, BRIAN J	
ART UNIT	**PAPER NUMBER**
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,271	SIRARD ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the response filed 3/16/2007, is acknowledged. The traversal is on the following ground(s).

Applicant argues:

1. That examination of all pending claims would not constitute a serious burden.

2. That the reference cited by the examiner to show a lack of unity does not apply because the reference discloses an intact flagellin protein instead of a flagellin protein or peptide fragment thereof which is truncated, mutated, or which has deletions, as is required by the claims.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, search and examination burden is not a factor in determining whether restriction is proper under PCT Rules 13.1 and 13.2.

Regarding argument 2, the restriction requirement and the determination of lack of unity were based on the claims as originally presented. Once lack of unity has been shown, restriction is proper. As originally presented the technical feature linking the groups was a flagellin protein. Furthermore, the claims read on full length flagellin proteins that occur naturally, as well as a whole organism, since the flagellin proteins are not isolated.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-18 are currently pending. Claims 1-11 and 18 are withdrawn as being drawn to non-elected inventions. Claims 12-17 are currently under examination.

Sequence Requirements

This application fails to comply with the requirements of 37 C.F.R. 1.821-1.825 because it contains amino acid sequences that are not identified. For example, pages 15, 17, and 18, contain sequences that are not identified. Appropriate sequence identifiers should be used to comply with sequence rules. The sequences in the specification should match the sequence listing and computer readable form (CRF) submitted with the application. Applicant is asked to review the specification for sequences that are not identified and correction is required.

Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing", a substitute paper copy of the "Sequence Listing", an amendment of the specification to insert appropriate sequence identifiers, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figures 6A and 6B. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The use of the trademarks ELISPOT and RPMI have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

It should be noted that the cited occurrences of improper use are only exemplary and applicant should review the specification to correct any other use of trademarks.

Claim Objections

Claim 14 is objected to because of the following informalities: the claim refers to the organism, *S. typhimurium*. The claim should refer to the full scientific name of the organism (i.e. *Salmonella typhimurium*), upon its first recitation in a claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 and 17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to mutant flagellin proteins which occur naturally.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to flagellin proteins, or peptide fragments thereof, that are truncated, mutated, or have deletions, wherein the protein (or peptide fragment thereof) retain the ability to induce an immune response. Dependent claims are further limited to said flagellin proteins, where the proteins have the ability to bind to intestinal or epithelial cell flagellin receptors and have immune signaling properties; where the protein includes at least one of the conserved regions (residues 1-190 and 354-494) of *Salmonella typhimurium*; and to the flagellin protein that includes at least on of the conserved regions of the N terminal sequence and the C terminal sequence of flagellin.

The specification discloses the sequence of the *Salmonella typhimurium* flagellin protein; however, the specification does not disclose the sequence or structural features of any flagellin proteins, or fragments thereof, that are truncated, mutated, or deleted. Since there is no limitation on what truncations, mutations, or deletions can be made to said protein, the claims encompass all proteins and peptide fragments that are in existence.

None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that applicant has possession the claimed invention.

The specification, however, does not disclose distinguishing and identifying features of a representative number of members of the genus of proteins to which the claims are drawn, so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of proteins. Moreover, the specification fails to disclose which amino acid residues are essential to the function of the protein (i.e. induce an immune response appropriate for therapy and to bind to flagellin receptors) or which amino acids might be replaced or removed so that the resultant mutant retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of proteins on which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of flagellin proteins, or fragments thereof, that are mutated, truncated, or which have deletions, while retaining the ability to induce an immune response appropriate for therapy.

The art shows that flagellin proteins, particularly *Salmonella* flagellin proteins are capable of inducing inflammatory responses, including increased levels of IL-6, IL-1β, and TNF-α (Wyant *et al.*, Infect. Immun., 67:3619-3624, 1999). The art also shows that there is a central

hypervariable region in the *Salmonella* flagellin proteins that allows for antigenic variation, while several highly conserved regions must be present (at least in *Salmonella dublin* flagellin proteins) to induce an immune response (Eaves-Pyles *et al.*, J. Immunol., 167:7009-7016, 2001, IDS filed 3/16/2007). The art does not show any that mutated flagellin proteins are useful in the treatment of particular diseases, especially those that are unrelated to *Salmonella* infection.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual

reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

Therefore, the full breadth of the claims does not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims 12-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for adjuvant compositions, does not reasonably provide enablement for flagellin proteins, or peptide fragments thereof, for use in therapy. The specification does not

enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary.

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. Thus, Applicant assumes a certain burden in establishing that inventions involving physiological activity are enabled. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The instant claims are drawn to flagellin proteins, or peptide fragments thereof, for use in therapy, wherein the flagellin protein, or fragment thereof is truncated, mutated, or has deletions therein, and wherein the flagellin retains the ability to induce an immune response.

Breadth of the claims: The claims encompass the use of virtually any peptide chain in all forms of therapy. The claims encompass immunotherapy as well as all other forms of disease treatment, including behavioral and physical therapy and treatments such as dialysis.

Guidance of the specification/The existence of working examples: The specification discloses that flagellin proteins are useful as adjuvants, particularly in inducing mucosal immunity. The specification does not provide any examples where flagellin proteins (in any form) are used to treat disease.

State of the art: The art shows that flagellin proteins, particularly *Salmonella* flagellin proteins are capable of inducing inflammatory responses, including increased levels of IL-6, IL-1β, and TNF-α (Wyant *et al.*, Infect. Immun., 67:3619-3624, 1999). The art also shows that there is a central hypervariable region in the *Salmonella* flagellin proteins that allows for antigenic variation, while several highly conserved regions must be present (at least in *Salmonella dublin* flagellin proteins) to induce an immune response (Eaves-Pyles *et al.*, J. Immunol., 167:7009-7016, 2001, IDS filed 3/16/2007). The art does not show any that mutated flagellin proteins are useful in the treatment of particular diseases, especially those that are unrelated to *Salmonella* infection.

There is no reason to expect that inducing an inflammatory response, or the use of flagellins, particularly fragments thereof (which includes single amino acids) as an adjuvant would treat disease.

Therefore, in view of the lack of support in the art and specification for the claims as drawn, it would require undue experimentation on the part of the skilled artisan to make and use the vaccine as claimed; therefore the claims are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the immune response" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 is rendered vague and indefinite by the phrase "flagellin protein or peptide fragment thereof is truncated, mutated or has deletions therein which allow it to retain its ability to induce the immune response." It is not clear whether the fragment of flagellin is truncated, mutated, or has deletions; or whether the flagellin protein is truncated, mutated, or deleted in order to get the fragment. In addition, the language of the claim implies that the flagellin protein

loses its ability to induce immune responses over time, and that the mutation will allow it to continue to induce an immune response.

Claim 14 is rendered vague and indefinite by the phrase "as shown underlined in Figure 8 herein." Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim.

Claim 17 is rendered vague and indefinite by the phrase "includes at least one of the conserved regions of the N terminal sequence and the C terminal sequence of flagellin." It is not clear which regions are considered "conserved." Further, it is not clear the what the limits of the N terminal sequence and the C terminal sequence are.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshioka *et al.* (J. Bacteriol., 177:1090-1093, 1995).

The instant claims are drawn to flagellin proteins, or peptide fragments thereof, that are truncated, mutated, or which have deletions, and which have the ability to induce an immune response (claim 12); wherein the flagellin proteins, or peptide fragments thereof, bind to intestinal or epithelial cell flagellin receptors and have immune signaling properties (claim 13); wherein the flagellin proteins, or peptide fragments thereof, include at least one of the conserved regions of residues 1-190 and 354-494 of *S. typhimurium* as shown in Figure 8 (claim 14); and wherein the flagellin proteins, or peptide fragments thereof, include at least one of the conserved

regions of the N terminal sequence and the C terminal sequence of flagellin (claim 17). It is noted that Figure 8 contains the sequence of SEQ ID NO:1.

Yoshioka *et al.* disclose several mutant flagellins and fragments thereof (see page 1091). In particular, the mutant flagellin from *S. typhimurium* strain SJW46 contains the conserved region (residues 1-194) of the *S. typhimurium* flagellin (see Figure 4). Regarding the limitation that the flagellin protein must bind to intestinal or epithelial cell flagellin receptors and have immune signaling properties, since the Patent Office does not have the facilities for examining and comparing applicant's composition with the compositions of the prior art reference, the burden is upon applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Claims 12-13 and 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Aderem *et al.* (US Patent Application Publication 2003/0044429, filed 4/17/2002, IDS filed 3/16/2007).

The instant claims are drawn to flagellin proteins, or peptide fragments thereof, that are truncated, mutated, or which have deletions, and which have the ability to induce an immune response (claim 12); wherein the flagellin proteins, or peptide fragments thereof, bind to intestinal or epithelial cell flagellin receptors and have immune signaling properties (claim 13); and wherein the flagellin proteins, or peptide fragments thereof, include at least one of the conserved regions of the N terminal sequence and the C terminal sequence of flagellin (claim 17). Additional claims are drawn to an adjuvant composition comprising the flagellin protein, or peptide fragments thereof, in combination with a pharmaceutically acceptable carrier, excipient, or diluent in a sterile pyrogen free form (claim 15); and a vaccine composition comprising the adjuvant and a target antigen (claim 16).

Aderem *et al.* disclose an immunomodulatory flagellin peptide, or modification thereof, which can be used to alter the immune response (paragraph 0053). Aderem *et al.* also disclose said altered flagellin peptide in combination with an antigen (paragraph 0062). Aderem *et al.* contemplate the use of said flagellin in a non-pyrogenic form, as evidenced by paragraphs 0110 and 0111, where they describe recombinant expression in a eukaryotic system (which would

necessarily be pyrogen-free), and subsequent purification. For delivery as a vaccine, the composition would necessarily include a pharmaceutically acceptable carrier. Regarding the limitation that the flagellin protein must bind to intestinal or epithelial cell flagellin receptors and have immune signaling properties, since the Patent Office does not have the facilities for examining and comparing applicant's composition with the compositions of the prior art reference, the burden is upon applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

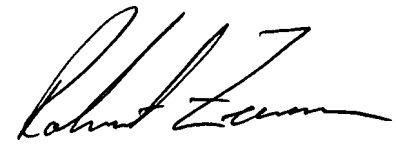
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian Gangle
AU 1645



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